Senate Bill 101

By: Senators Cowsert of the 46th, Pearson of the 51st, Heath of the 31st, Hill of the 32nd and Wiles of the 37th

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 1 of Title 51 of the Official Code of Georgia Annotated, relating to general provisions regarding torts, so as to limit liability for certain drug and medical device manufacturers and sellers under certain circumstances; to provide for definitions; to provide for exceptions; to provide for the supplementary nature of the Code section; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 1 of Title 51 of the Official Code of Georgia Annotated, relating to general provisions regarding torts, is amended by adding a new Code section to read as follows:

"51-1-11.2.

(a) As used in this Code section, the term:

(1) 'Device' shall have the same meaning as set forth in Code Section 26-4-5.

(2) 'Drug' shall have the same meaning as set forth in Code Section 26-4-5.

(3) 'Entity' means an individual, corporation, partnership, or association which has its United States corporate headquarters, principal place of research and development or manufacturing, or a research and development facility in this state or which employs more than 200 Georgia residents for manufacturing or research and development purposes.

(4) 'FDA' means the United States Food and Drug Administration.

(5) 'Manufacturer or seller' means an entity which is engaged in the manufacture, distribution, or sale of drugs or devices.

(6) 'Research and development' means experimental or laboratory activity for the ultimate purpose of developing new products, improving existing products, or developing new uses for existing products.

(b) A manufacturer or seller shall be immune from civil liability for any claim based on strict liability for a defect in the design of a drug or device if the drug or device was

approved for safety and efficacy by the FDA at the time the drug or device left the control of the manufacturer or seller. Approval pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act shall not be considered approval for safety and efficacy for the purposes of this Code section.

(c) A manufacturer or seller shall be immune from civil liability for any claim based on the failure to adequately warn of risk of a drug or device if labeling of the drug or device was made available to the consumer or prescribing person and such labeling was in compliance with the FDA's applicable standards at the time the drug or device left the control of the manufacturer or seller.

(d) This Code section shall not apply to any cause of action if the FDA determined that the manufacturer or seller committed a fraud on the FDA with regard to the product at issue in the lawsuit. Notwithstanding any other provision of law, with respect to any claim referenced in subsections (b) and (c) of this Code section not barred as of July 1, 2009, if the FDA officially determines that a fraud on the FDA has occurred, the limitation period shall not begin to run until after such determination.

(e) This Code section shall be supplemental to all other provisions of laws that provide defenses for manufacturers and sellers.″

SECTION 2.

All laws and parts of laws in conflict with this Act are repealed.